

How dementia and neurodegenerative disease clinical research networks have enhanced research delivery in England

In 2005 the Government established a clinical research network in dementia and neurodegenerative diseases to increase and improve research in an area of unmet need. Since its creation, the Dementias and Neurodegenerative Diseases Research Network (DeNDRoN) has facilitated a 300% increase in the number of the National Health Service trusts recruiting people to dementia and neurodegeneration research, a 500% increase in the number of open studies each year, and a 600% increase in the number of people taking part in studies. This article summarizes the increased activity and improvements in performance delivered since 2005; describes some of the people networks through which this has been delivered; and describes how the network is evolving as part of the reorganization of the National Institute for Health Research Clinical Research Network.

Keywords: clinical trials • dementia • DeNDRoN • network • neurodegeneration • NHS • NIHR • research

Background

The National Health Service (NHS) in England has been developing networks to increase its capabilities and capacity to deliver clinical research since the establishment of the National Cancer Research Network (NCRN) in 2001. Following successful evaluation of the NCRN, first a mental health research network, then networks in diabetes, medicines for children, stroke and dementias and neurodegenerative diseases (Dementias and Neurodegenerative Diseases Research Network [DeNDRoN]) were established between 2004 and 2006. The success of these networks, for example, in improving the speed, cost and delivery of research sponsored by pharmaceutical companies [1] led to the incorporation of this model in the Government's research strategy in 2006 [2]. A Comprehensive Clinical Research Network and a Primary Care Research Network were established to complement the six existing networks; together making the new National Institute for Health Research (NIHR) Clinical Research Network.

The DeNDRoN was established in 2005, covering 50% of England. As described by the authors elsewhere [1] it took 3 years to fully implement, with a steady-state workforce of front-line research support staff recruited by 2008. A primary aim of the network is to integrate research with everyday clinical practice. These front-line staff are embedded in the NHS and work closely with clinical teams to facilitate the identification and recruitment of people for clinical studies.

The impact of the network model was already measurable by 2007 as demonstrated in the performance of the PD MED trial, a randomized assessment of the relative clinical and cost-effectiveness of classes of drugs for Parkinson's disease – then the largest ever Parkinson's disease trial in the UK. From 2007 recruitment to PD MED doubled in the areas of the country supported by the network compared with those areas without network support [3]. As the network developed over the 6 years to 2011 it successfully increased the capacity of the NHS to deliver dementia and neurodegenerative diseases

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research. The rate of growth in the number of NHS sites delivering commercial research in network areas was double that in the rest of England; and network support sites recruited twice as many people per study compared with non-network sites [4].

In the 3 years since the publication of the review by Kotting *et al.* [4] the network has developed both in terms of its capacity and capabilities, and its maturity. In this paper we provide an update on the activity and performance of the network; describe some of the key people networks through which dementia and neurodegeneration clinical research is delivered in the UK; and discuss the evolution of the network as part of the newly reorganised NIHR Clinical Research Network.

An update on activity & performance since 2010/2011

Since 2010/2011 dementia and neurodegeneration research activity in the NHS has continued to grow steadily. Year-on-year the number of new studies opening has increased, reaching 79 in 2013/2014, taking the total number of studies open during the year to a record 18 (there were 155 in 2010/2011 and 73 in 2007/2008). The number of NHS trusts supporting recruitment to these studies has increased from 171 in 2010/2011 to more than 200 in 2013/2014. The number of people now participating in dementia and neurodegeneration research reached an all-time high of 13,400 in 2013/2014. This represents approximately 4.4% of people diagnosed with dementia (from less than 1% when DeNDRoN was established), and represents significant progress towards the Government's ambition for 10% of people with dementia to be involved in research [NIHR CLINICAL RESEARCH NETWORK PORTFOLIO DATABASE, DATA ON FILE].

The growth in dementia and neurodegeneration research activity in the NHS is encouraging, but equally important is the fact that performance of these studies has continued to improve as the activity has increased. From a baseline of approximately 30% of studies meeting their recruitment targets within pre-agreed timescales [5] by 2011/2012 79% of studies on the DeNDRoN portfolio were completing on time to target, and in 2013/2014 the figure was 85%.

Understanding DeNDRoN through its people networks

Dementias and a range of other neurodegenerative diseases are increasingly understood to have commonalities in underlying mechanisms, patient experience, and symptoms and management of these diseases is increasingly multidisciplinary and converging over time. Advances in understanding of these diseases and new treatments are likely to come from interdisciplinary

research. DeNDRoN has, therefore, focused on building a broad community of interest spanning a range of neurodegenerative diseases, from a variety of specialties and research interests.

An analysis of government- and third sector-funded dementia research between 2008 and 2013 shows that neurologists (28% of studies) and old-age psychiatrists (21%) are the lead applicants on approximately half the dementia and neurodegeneration studies on the NIHR Clinical Research Network portfolio. In total, 12% of studies are led by other medical specialties, 12% by psychologists and 9% by nurses and allied health professionals. A total of 15% are led by basic scientists, with 3% unclassified.

This community is supported through managed networks of investigators and research support staff, and of systems and processes to facilitate them working together locally, regionally and nationally to remove the barriers to developing and delivering high-quality dementia and neurodegenerative diseases research across a range of healthcare settings including acute and mental health NHS trusts and in primary care.

Within this broad community of interest there are a number of more granular communities of practice. Local and national network management, and development of the capacity of the NHS to support research, is facilitated at the level of the DeNDRoN community. For the purposes of supporting the development and delivery of the DeNDRoN Portfolio, the key clinical networks are organised at the level of communities of practice, according to the diseases they specialize in: dementia, Parkinson's, motor neurone disease and Huntington's. Within these communities of practice a number of networks have developed to support delivery of different outcomes across the community (Figure 1).

Evolution of DeNDRoN as part of the re-organized NIHR Clinical Research Network

Since 2008 the NIHR Clinical Research Network has comprised eight national network coordinating centers – of which the DeNDRoN coordinating center is one – and 102 Local Research Networks – of which seven have been DeNDRoN. From 1 April 2014 the NIHR Clinical Research Network adopted a new organizational structure with one integrated national coordinating center and 15 Local Clinician Research Networks (LCRNs) that provide regional infrastructure to support research in all portfolio areas [6].

One of the challenges of moving to the new system will be navigating tensions between realising the benefits to be gained from consolidating the existing networks and maintaining topic-specific ways of working that have contributed to their success. One size rarely fits all and delivering research is not a homogenous

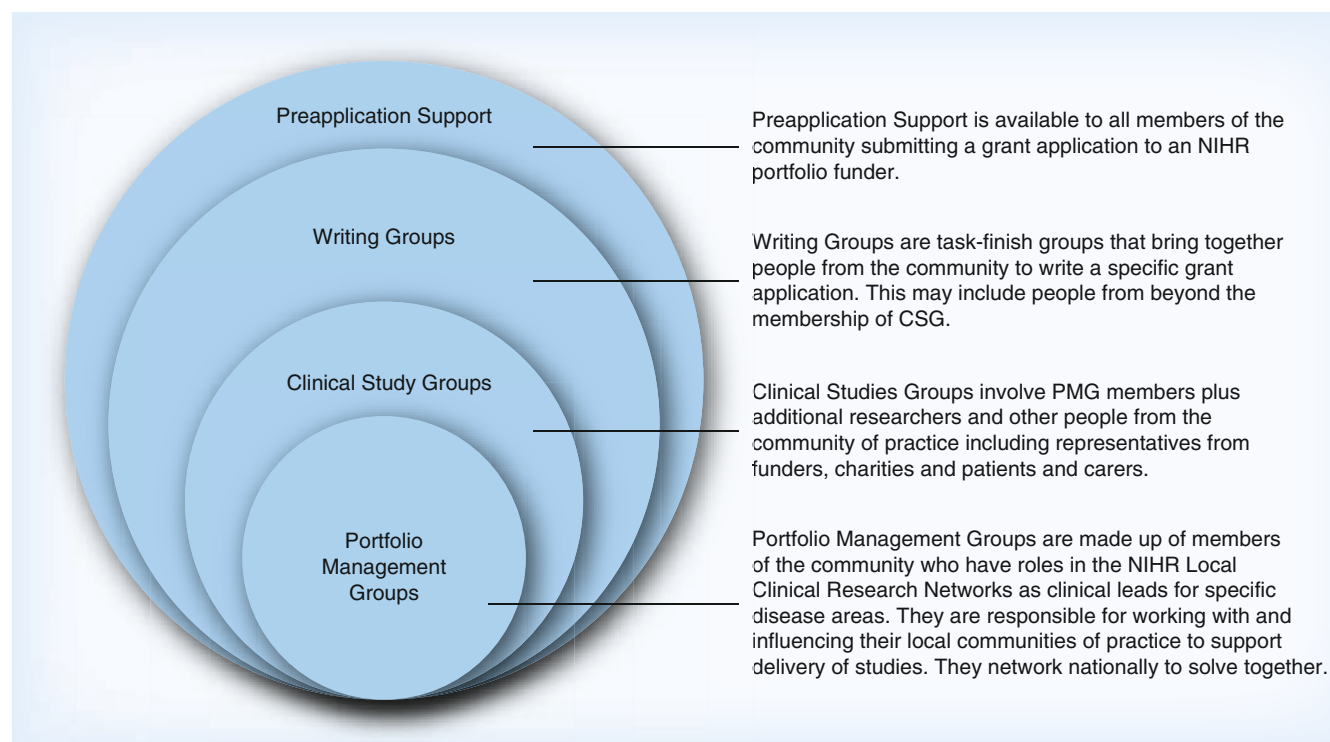


Figure 1. Organization of DeNDRoN clinical academic people networks.

CSG: Clinical Studies Groups; NIHR: National Institute for Health Research; PMG: Portfolio Management Groups.

process. In setting up DeNDRoN following the blueprint of the National Cancer Research Network, throughout 2006 and 2007 the authors were often confronted with the realization that the substrate on which the two networks were being built were sufficiently different, what was successful for one would not necessarily be so for the other. The demographics of typical research volunteers; the target populations (incident versus prevalent); the underlying NHS clinical services from which they are recruited (highly structured cancer clinical networks vs dementia services characterized by huge variation in quality and service organization); and the research funding environment (there was and remains no equivalent of the National Cancer Research Institute in the DeNDRoN field) all meant appropriate differences between the organization of the NCRN and DeNDRoN emerged, as they did between the other networks. Even within a single topic area local variation was also necessary. Variations in the organization of clinical services, geographical differences and research interests and traditions all led to appropriate variation in the models adopted by the seven DeNDRoN Local Research Networks.

The variance in delivery and the large number of networks is often cited as a reason for the need to change the organization of the NIHR Clinical Research Network although an interpretation of the status quo was that localism – geographic and disease – had been

allowed to drive the evolution of the networks so that they met their local needs within a broader national framework.

The previous Culyer system had been deemed too ‘local’ back in 2004 and individual NHS trusts sometimes perceived to be poor guardians of the NHS’s investment in the concordat [7–9]. The response was a managed network, but as it evolved did it also grow to become too ‘local’ itself? The new organization of the NIHR Clinical Research Network should have some significant benefits and is a highly locally driven enterprise with key accountability for delivery resting with the lead NHS trusts of the 15 Local Clinical Research Networks. However, the number of loci has undoubtedly decreased, and with it arguably the ability of the network to respond in any one instance to local and disease need. Herein lies a key challenge for the dementia and neurodegenerative diseases research community over the next few years and those leading the establishment of the new NIHR Clinical Research Network: to identify key synergies and targets for efficiencies, while retaining the specialist skills, ways of working and enthusiasm that have been built over the past 8 years across the DeNDRoN community.

Dementias and neurodegeneration (DeNDRoN) is a research specialty area within the new organizational structure, rather than an independent network, and the clinical expertise that has been developed and

put in place over the years will continue to focus on dementias and neurodegeneration research within the new generic arrangements. The restructuring brings DeNDRoN into an operational division, locally and nationally, with the specialties of mental health and neurological disorders. This should enable creation of stronger links between the people networks in these related areas, providing access to a wider range of expertise and enable a greater sharing of resources across this broader community.

The transition to these new arrangements is taking place throughout 2014. The workforce in the previous DeNDRoN Local Research Networks has largely been transitioned into the 15 new NIHR Local Clinical Research Networks. The new outcomes and operating framework for the LCRNs contains a range of deliverables for 2014/2015 specific to the dementias and neurodegeneration (DeNDRoN) specialty designed to support a smooth transition to the new arrangements.

Early signs are that the LCRNs' response to these deliverables is encouraging. LCRNs are required to identify and support local clinical leaders in each of the main disease areas in the DeNDRoN portfolio, and facilitate these research leaders coming together in national fora to promote learning across regions. These local leadership arrangements are still being finalized, but the existing DeNDRoN clinical leaders are largely reporting good engagement and support from the leaders of the new LCRNs. The national Portfolio Management Groups will continue to function within the new system, bringing together local leaders to identify and remove barriers to successful delivery of studies by sharing intelligence between sites and across studies.

Progress to date

In its first incarnation as the Dementias and Neurodegenerative Diseases Research Network, DeNDRoN has been successful. It has increased opportunities for patients and healthcare professionals from all parts of the country to be able to participate in and benefit from clinical research: there has been a 300% increase in the number of NHS trusts recruiting to dementia and neurodegeneration studies, a 500% increase in the number of studies open each year, and a 600% increase in the number of people taking part in studies. It has increased integration of health research and patient care by developing a dedicated research support workforce working alongside clinical colleagues throughout the NHS. It has enabled the NHS to better meet the dementia and neurodegeneration research needs of industry, and improved the quality, speed and coordination of clinical research: the proportion of studies meeting their recruitment targets within agreed timescales has risen from 30 to 85%. Perhaps most

importantly it has encouraged and fostered increasing collaboration across the dementia, Parkinson's disease, Huntington's disease and motor neurone disease research communities, and between the key groups of people that make delivery of research possible: people affected by these conditions, clinicians, researchers and research funders.

Future perspective

In its new incarnation as a research specialty within the new-look NIHR Clinical Research Network, DeNDRoN is in a position both to extend its learning from the first 8 years and harness the expertise and experience of colleagues from other areas of the clinical research network to drive the further growth in capacity that is required to meet the demand for clinical research in dementia and neurodegenerative disease. Having responded to the Prime Minister's challenge [10] and the doubling of Government and charity funding dementia research to GBP£64.3m between 2009/2010 in 2012/2013 [11], the DeNDRoN community now needs to grasp the opportunities presented by the continued political support for research in this field and by the reorganization of the NIHR Clinical Research Network as the Government proposes to double funding again over the next 10 years.

Key areas for future review of the clinical research infrastructure for dementia and neurodegeneration research include assessing the success of the transition to the new network structures and evaluating how the people networks developed through the NIHR have responded to the increased political salience and funding.

In a wider context, dementia and neurodegeneration research has recently become a global priority with the 2013, G8 Dementia Summit agreeing to appoint a World Dementia Envoy to draw together international expertise to stimulate innovation and to coordinate international efforts to attract new sources of finance, including exploring the possibility of developing a private and philanthropic fund to support global dementia innovation. The recognition that solving the difficult challenges posed by these diseases will require much greater cooperation and collaboration than there has previously been means that DeNDRoN expertise developed in the first phases of networking will now be immersed in a much more diverse world than it has been previously, spanning translational research and feeding through to innovation and implementation activities.

Disclaimer

The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health.

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Executive summary

- The positive impact of the clinical research network model for dementia and neurodegenerative diseases was demonstrated within 2 years.
- The network has increased the capabilities and capacity of the National Health Service to deliver dementia and neurodegenerative diseases research.
- The number of National Health Service trusts supporting recruitment to dementia and neurodegenerative diseases studies has increased by 300% to over 200.
- The number of new studies opening has increased year-on-year to a high of 79 in 2013/2014.
- The proportion of studies meeting their recruitment targets within agreed timescales has risen from 30 to 85%.
- The number of people now participating in dementia and neurodegeneration research reached an all-time high of 13,400 in 2013/2014, approximately 4.4% of people diagnosed with dementia.
- Increases in capacity and improvements in performance have been collaboratively lead through broad, multidisciplinary networks of investigators.
- Dementias and Neurodegenerative Diseases Research Network is changing from an independent network to a research specialty area within the newly reorganized National Institute for Health Research Clinical Research Network.
- New organization offers opportunity to grow and strengthen the Dementias and Neurodegenerative Diseases Research Network people networks.

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