

IMPLEMENTING RESEARCH WITHIN THE NHS:
COLLABORATION, CHALLENGES AND IMPLICATIONS

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I completed the MSc in Medical Anthropology at Oxford in 2004. Many of the biological aspects of this MSc were inspired by content from the Oxford BA in Human Sciences, which I had previously studied at St John's College. I later continued on the academic path for another year through the MSc in Epidemiology at the London School of Hygiene & Tropical Medicine. Since May 2007 I have been working in a clinical research team within the National Health Service, part of the National Institute for Health Research (NIHR). I joined the Dementias & Neurodegenerative Diseases Research Network (DeNDRoN), part of the NIHR Clinical Research Network and funded by the Department of Health in England, in Oxford shortly after the first few team members were recruited. The reflections presented in this article are based on my personal experience with the local team in the Thames Valley region in England (Berkshire, Buckinghamshire, Leicestershire, Milton Keynes, Northamptonshire and Oxfordshire).

When I was invited to contribute to the conference celebrating 'Ten years of Medical Anthropology at Oxford', it seemed natural to select the panel entitled (somewhat tongue in cheek) 'career paths into the real world'. Indeed, the UK's National Health Service would certainly seem to bring together many aspects of the so-called 'real world'. Not a week goes by without the NHS being mentioned in the British news media. The system affects all residents and tax-payers in Britain, evoking strong emotion and fierce debate.

On 5th July 2014, the NHS celebrated its 66th birthday. In recent years the Department of Health has invested in and committed itself to research, specifically towards optimizing the huge potential of the NHS as a host of more and better clinical research. The 'Best Research for Best Health' strategy for NHS R&D (Department of Health 2006) outlined the vision for the NHS contribution to health research in England. As part of this new strategy, the National Institute for Health Research (NIHR) was launched, its vision being to 'improve the health and wealth of the nation through research' (ibid.).

Over the past seven years I have worked in the NIHR Clinical Research Network (CRN), in the area of dementias and neurodegeneration (DeNDRoN). The NIHR CRN is funded by the Department of Health in England, providing a service of research delivery in the NHS. Until 1 April 2014, DeNDRoN was known as the Dementias & Neurodegenerative Diseases Research Network. DeNDRoN now refers to one of thirty research ‘specialties’ in the NIHR CRN.¹ In this article, after expanding on DeNDRoN’s role and origins as part of the NIHR, I will describe a few ways in which its participants have been working to implement research within the NHS. I will evoke some specific areas of work where my background has helped me to develop my role. Medical Anthropology and Human Sciences have been useful through their promotion of collaboration across disciplinary boundaries, and their stress on the need to appreciate the different perspectives of people who contribute to the research process. I will conclude by elaborating further on some of the challenges and implications of the growth of NHS-based clinical research and the changing role of the NHS.

National health institutes and research networks

Often referred to as the ‘research arm’ of the NHS, the NIHR was established in April 2006 to provide the framework for development of the NHS in England as a national research facility. The NIHR has several functions, including commissioning research focused on improving health and social care, and providing the facilities and people to support the conducting of studies within the NHS. The latter purpose is mainly facilitated by the NIHR CRN, of which DeNDRoN is a part.

The NIHR CRN was developed based on the success of the cancer research network model, established in 2001. Since then, the number of cancer patients in the UK participating in clinical studies has increased from one in 26 to around one in six patients diagnosed (Cancer Research

¹ This article was written before 1 April 2014, when the National Institute for Health Research (NIHR) Clinical Research Network was reconfigured. The various research networks operating in the Thames Valley region before 1 April 2014 (including Thames Valley DeNDRoN) are now part of the NIHR Clinical Research Network: Thames Valley and South Midlands. As a result, some of the terminology used here refers to the structure that was in place before 1 April 2014.

Specialty, NIHR CRN 2013). By 2010, 18 out of every 100 newly diagnosed patients were taking part in cancer studies. Patient participation levels in cancer research in the UK are currently the highest in the world (National Institute for Health Research 2011).

The NIHR CRN was established as part of a response to concerns from the pharmaceutical industry over whether the UK was a suitable place to carry out clinical trials in the longer term. The number of clinical trials taking place in the UK has declined rapidly in recent years, from 6% of the global total in 2000 to 1.4% in 2010 (Walsh 2011). This is largely due to the excessive time and costs involved in completing a trial in the UK compared to other countries such as India or China. The NIHR CRN also aimed to maximise the research potential of the NHS, as host to vast amounts of health data spanning several decades, and to build the UK's reputation as a host for clinical research.

The NIHR CRN has a number of objectives. First, it aims to ensure that patients and healthcare professionals from all parts of the country are able to participate in clinical research. In addition, it seeks to increase collaboration with industry partners to make sure that the NHS can meet the health research needs of industry. An important aim is for NHS Trusts to act as study sites around the country. A key selling point for encouraging NHS Trusts to act as study sites is that referring NHS Trusts receive an income for each patient who takes part, and this income tends to be greater for industry-sponsored studies. This is part of the rationale for the NIHR CRN, which represents a business model with the aim of attracting pharmaceutical investment to the country. Finally, it aims to improve the amount and quality of clinical research in the NHS by enabling quicker and more effective recruitment to studies.

The main mechanism through which the NIHR is encouraging better research is the promotion of patient and public involvement (PPI) at different stages of the research process. Greater public involvement can help to improve the practical aspects of research protocols by enhancing participants' comfort, or by including study outcomes that are more relevant and meaningful to

patients and their carers. In dementia studies, for example, these may include measures of the burden experienced by carers. The role of PPI will be considered in more detail below.

The Dementias & Neurodegenerative Diseases Research Network

The remainder of this article will focus on DeNDRoN, although services and activities tend to reflect the type of support available in other research areas and in the NIHR CRN as a whole. DeNDRoN focuses on research into dementias, Huntington's, Parkinson's, and motor neurone disease. DeNDRoN aims to increase levels of patient and professional participation in research, and to increase the overall level of industry investment in clinical research in the NHS.

DeNDRoN staff predominantly include clinicians (often research nurses), administrative and managerial staff. DeNDRoN staff do not carry out their own research. Rather, the DeNDRoN team acts as a service provider at an operational level. DeNDRoN and the NIHR's remit is 'to support and conduct randomised controlled trials and other well-designed studies for commercial and non-commercial sponsors' (Department of Health 2006). DeNDRoN provides support for a variety of study designs apart from clinical trials (e.g. observational studies, patient registries, data banks). For example, our local team has supported questionnaires about the burden of caregiving, trials of drug treatments, psychosocial interventions and exercise programmes, and brain donation studies. DeNDRoN provides a number of services to facilitate research, from study set-up through to recruitment of participants and study 'delivery', i.e. data collection during study visits. Some of our day-to-day activities include local research governance (ethics and NHS) approvals and contract negotiations. DeNDRoN's main performance measure is study participant recruitment targets.

Researchers and research organisations may receive DeNDRoN support if their study fits the criteria for adoption into the NIHR 'Portfolio'. In general, the principal determinant of priority for inclusion in the portfolio is the source of research funding. Studies that are automatically eligible with a high priority for DeNDRoN support are those that have the majority of their research funding

provided by the NIHR, other areas of Government, and NIHR non-commercial 'Partners'. The latter include medical charities and large funding bodies, and represent those organisations that award research funds according to three particular criteria. First, they must do through open competition across England with high-quality peer review. Secondly, the research must be of clear value to the NHS. Determination of such 'value' is made by a panel that includes experienced academic researchers in the field of study and lay representatives. The judgment of the panel is deemed sufficient to satisfy this criterion. Finally, the award must take account of Department of Health and NHS priorities and needs as reflected in their research funding strategies. All studies funded by industry or non-NIHR partners are adopted into the portfolio based upon UK study feasibility and local capability. All studies must already have full research funding before they can be included in the portfolio.

Ultimately, DeNDRoN's main target audience is the community of people living with neurodegenerative conditions who may be eligible to take part in studies. What motivates people to take part in research? The Health Experiences Research Group in the Department of Primary Care Health Sciences at the University of Oxford is a key driver of research in this area, and its findings contribute to the content of the Health Talk Online website (DIPEX charity 2001). Some views about motivations for participation have been gathered by Louise Locock and Lorraine Smith (Locock and Smith 2011). Two main categories of reasons for taking part are distinguished: the first is about helping others and medical science, while the second is about the personal benefits.

Much research suggests that people take part in clinical studies mostly for altruistic reasons. Locock and Smith's qualitative study (*ibid.*), using in-depth semi-structured interviews conducted at home, revealed several altruistic reasons for participation. Some felt a general wish to support medical science and improve knowledge. Others suggested that participation could help people feel that something positive was coming out of an otherwise distressing illness. Others also evoked a desire to 'give something back', a reflection of their gratitude for the care they had received or for

having lived longer than expected in some cases. This desire suggests the idea of repaying a debt to other patients who had volunteered for research in the past, or a debt to the NHS as an institution.

This sense of reciprocity between the NHS and its users might suggest parallels with anthropological analyses of gift-giving. In his classic text, Marcel Mauss ([1925] 1954) presented gift-giving as a ‘total social fact’ that is all-encompassing, both socially and morally. Is research participation comparable to gift-giving in the Maussian sense? A current Parkinson’s study is inviting relatives of people with Parkinson’s to take part. It is possible that research participation by these relatives involves the kinds of social reciprocity to which Marcel Mauss referred, where interpersonal connection and mutual responsibility arise. However, research participation mainly tends to link people who are unknown to each other. The anonymous nature of research participation is a significant departure from traditional gift-giving. These participants may perhaps inhabit the ‘imagined’ communities referred to by Anderson (1991), connecting people through their comparable experiences or circumstances.

By contrast, reasons for research participation involving personal benefits included the opportunity to have access to a new drug or treatment (Locock and Smith 2011). Learning and acquiring more information about the condition was also cited. Moreover, opportunities to be screened (hoping either to be reassured or to get an early diagnosis), or to gain faster or more specialized access to care, were mentioned. Finally came the participant’s interest or curiosity in the research itself. Medical anthropology has helped me appreciate better this aspect of clinical research in drawing my attention to the experience and narrative of the person rather than to the disease category of a study. At the same time, understanding what may motivate people to take part in studies can help teams like DeNDRoN achieve one of their main ‘bottom line’ objectives, namely reaching recruitment targets.

Increasing participation levels of service users and clinical staff in research is clearly a long-term project. In the following section I describe some approaches used by the DeNDRoN team

(including myself) to enable the implementation of research within the NHS, as well as some of the challenges involved.

Bridging perspectives: Patient and Public Involvement (PPI)

The nature of any network is to bring people together. DeNDRoN aims to encourage doctors, nurses, patients, carers, researchers, funders, academics and NHS trusts to work effectively together to improve the amount and quality of NHS-based research in dementia and neurodegenerative diseases. Such a collaborative effort may sound ambitious. Needless to say, it isn't always easy to make this happen in the 'real world'.

Medical Anthropology and Human Sciences at Oxford both have a special focus on integrating different perspectives and disciplines. Despite hearing many people talk about 'collaboration' and 'working together', it is perhaps not surprising that individuals and organizations do not always act in this way. Collaboration does happen, of course, but it needs constant reminders and promotion. Although personalities and the quality of relationships may present challenges, a focus on developing good rapport, regular communication and a good understanding of what partners want can be helpful. At the same time, encouraging communication across multiple perspectives can avoid duplication of effort or, to use the commonly employed expression, 're-inventing the wheel'.

The involvement of patients, carers and members of the public in all stages of the NHS research process is called 'Patient and Public Involvement' (PPI). PPI brings together the perspectives of the public with the perspectives of people who have a professional role in health research. PPI includes, for example, members of the public working with research funders to prioritise research, offering advice as members of a project steering group, or commenting on and developing research information materials. PPI is an important part of the NIHR agenda, and it now forms an essential part of NIHR grant applications – although not without a period of adaptation. Initially, there was perhaps a perception whereby some researchers viewed consulting patients and

members of the public as an additional burden, presenting possible delays in the development of proposals. As a result, there has been a tendency to involve the public in a tokenistic way, reducing PPI to a tick-box exercise as part of a grant application.

As part of my work with DeNDRoN, I have facilitated in-depth interviews and focus groups with lay members of PPI groups to guide the development and design of studies. Our team also often involves patients and carers in training and education events for NHS staff, as either speakers or facilitators. This enables the patient perspective to form part of discussions. We use such events to inform our clinical audiences, which tend to bring together different roles within local NHS teams (e.g. nurses, doctors, occupational therapists, physiotherapists, psychologists, social workers), about studies that are recruiting at that time.

Often the most powerful and memorable talks at these research events are given by patients or carers. It is always refreshing to see ‘lay’ people, experts through their experience of a condition, guiding and advising seasoned professionals; however, such a coming together of researchers with lay ‘experts’ can generate strong emotion. For example, until national NICE guidelines for the prescribing of dementia drug treatments changed in 2011, many people were angered by the lack of availability of drug treatments through the NHS for the mild or severe stages of Alzheimer’s disease. The ‘DOMINO-AD’ trial (Donepezil and Memantine in moderate to severe cases of Alzheimer’s disease) aimed to test the efficacy of the continued use of Donepezil, or combination therapy with Memantine, for patients after they had reached the severe stage of Alzheimer’s. The study generated some initial frustration among patients and carers who were possible candidates for this study, as they believed that the treatments should already have been available through the NHS. What emerged through this exchange was that staff needed to explain the research process, and particularly the need to gather evidence of cost-effectiveness.

Involvement in PPI can be empowering for patients, but also frustrating at times. Requests for feedback for study results are common, yet this information is often only available after considerable

time and delays. I am often asked to provide ‘good news’ stories for local medical charity newsletters, yet positive results do not occur very frequently. Over the past few years, there have been new treatments that have excited the local dementia community, but unfortunately these have not yet provided the long awaited ‘breakthrough’. There may also be instances where certain findings are not made publicly available if they do not align with the commercial interests of the sponsoring research organisation. For example, the largest study performed to date of Donepezil (which is approved for Alzheimer’s disease) for Parkinson’s disease dementia was completed in 2005, but it was not fully reported until 2012. The study, sponsored by Eisai Ltd., was completed prior to current US legislation on trial registration that requires applicable studies, following their initial registration on the clinicaltrials.gov database, to submit their results no later than twelve months after the date that the final participant completed the study. Until 2012, the only public record of the Donepezil study was a poster presented in Salzburg in March 2007, which showed mixed results. A full report was published in August 2012, where the authors concluded that ‘this global study did not meet its planned primary objectives’ (Dubois et al. 2012). Such delays and biases in the publication of results can affect the integrity of our approach with participants. In the case of incomplete public reporting of results, we fail to keep our promise to participants that their contribution will help improve knowledge about a condition or treatment.

Failure of communication happens both ways, in that the public seems to be more keen on research than NHS clinicians think they are. A poll on this issue, commissioned by the Association of Medical Research Charities, was carried out in June 2011 (AMRC 2011). Of the 990 people consulted, 97% believed it was important for the NHS to support medical research, and 93% wanted their local NHS to be encouraged or required to support research. Based on my experience of working with DeNDRoN, I argue that there has been a mismatch between this public demand for research and the perception of NHS clinicians. Research can sometimes be the only hope for patients and carers living with neurodegenerative conditions like Alzheimer’s or Parkinson’s. We still do not

know what causes these conditions, and current treatments only offer symptomatic relief. One could say that NHS Trusts therefore have a moral incentive to become more research-active in these areas.

Culture change?

A thriving ‘research culture’ in the NHS was one of the goals of the NIHR R&D strategy published in 2006. This notion of a ‘research culture’ has been used consistently by Network staff to describe the higher levels of clinician and patient participation in research that they are promoting. The term ‘culture’ is commonly used outside of anthropology and should be seen as fluid in this context. The notion of a ‘research culture’ may be interpreted as part of a drive to normalize and make more routine the process of engagement with research, which includes participation in studies. This language is perhaps used specifically to serve a purpose. The term ‘culture’, and references to ‘cultural change’, are sufficiently vague and accessible for stakeholders to grasp the idea that the project is about a greater social good, akin to a social movement. This in turn implies a call to action.

While progress has been made, the goal of a ‘thriving research culture’ in the NHS, as outlined in the NIHR R&D strategy (Department of Health 2006), has yet to be achieved. Implementing research in the context of resistance to change by NHS staff has been a challenge. There are certainly areas where clinicians have developed the habit of asking their patients about research involvement, but this still depends on the clinician and is variable across local teams. Many clinicians are quick to welcome research in principle, but are perhaps reluctant to add to their already overburdened workloads. As part of our local team’s strategy, we offer services to clinicians such as memory clinic assessments (e.g. memory tests, the ability to carry out everyday activities), which help to inform their patients’ treatment plans. In return, DeNDRoN staff have greater opportunities to approach patients about possible research involvement. I manage a database that links the routine prescribing of dementia drugs with the identification of people who are happy to be contacted about

suitable research opportunities. Thus, through an essential service (prescribing), research is made more visible and becomes part of routine clinical practice.

The development of a ‘culture’ of participation in research suggests a collective responsibility in making research involvement part of a commitment that extends beyond clinical or scientific boundaries. There are specific potential implications of increasing levels of participation in neurodegenerative disease research. Members of the public might need to consider their mortality, or that of a loved one, and declining mental capacity and its consequences. One could draw a parallel with blood and organ donation campaigns, but with NHS service users instead being asked to engage in a social contract in the production of research. Organ donation for purposes of research differs from donation for transplants in a number of ways, most notably the absence of a single recipient in the former. In addition, while transplant donation aims to save a life, donations for research aim to improve our knowledge base. While this altruistic calling is perhaps emphasized by research participants and those who seek to recruit them, in practical terms the future of the NIHR Clinical Research Network will be performance-driven. Repeat funding for local teams is set to depend on key factors such as recruitment times and targets.

In the move towards an NHS ‘research culture’, it has been interesting to observe a fine balance between the pressure to recruit sufficient study participants and the clinical sensitivity required to deal with people with neurodegenerative disease. There is clearly a need to avoid instrumentalizing patients and carers by reducing study participants to recruitment figures. The term ‘accrual’ was previously used to describe the number of participants recruited for a study or region. Use of this term (frequently used in accounting) is now discouraged, as it was perceived to depersonalize patients (and arguably reduce them to the financial value they brought to the NHS). These observations parallel Pizza’s (2012) ethnographic work on the social and political processes that underpin early diagnoses of Alzheimer’s disease, which similarly highlights the implications of language use and clinical assessment methods on patient experience.

In March 2013, the NHS Constitution was amended in favour of further establishing a ‘research culture’. The Constitution now includes the following pledges to citizens (NHS Choices 2013: 8):

- ‘to anonymise the information collected during the course of your treatment and use it to support research and improve care for others.’
- ‘where identifiable information has to be used, to give you the chance to object wherever possible’
- ‘to inform you of research studies in which you may be eligible to participate’

Such commitments will facilitate the work of the NIHR CRN. There is no doubt that this shift could lead to significant benefits, but significant challenges will remain. The public will need to be adequately informed about possible secondary uses of their medical data for research. They will need to be offered clear and effective opt-out procedures. A clear understanding about data anonymisation and the likelihood of re-identification will also be required (Brown et al. 2010).

The NIHR’s ambition is for the NHS to become a national health *and research* service. Some NIHR members argue that a ‘research-active’ status will act as a marker of quality for NHS Trusts, enhancing their reputation and image and in turn increasing the organization’s attractiveness to local service-users. The role of the NHS will change to allow researchers greater access to patient health information. The challenge is to develop systems that efficiently enable this access, while preserving confidentiality and anonymity. With these changes in place, a ‘culture’ of high-quality research within the NHS could be realized, reaching towards the wider goal of better care for patients.

The views expressed in this article are those of the author and do not represent the views of DeNDRoN or the National Institute for Health Research.

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