Editorial for *Dementia*

**Making progress in psychosocial research in dementia**

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Advocacy organisations and the research community have long complained about the paucity of funding for dementia research in the UK. Funding that did exist was viewed by some as failing to address significant gaps in knowledge by favouring biomedical studies rather than health services or social care research.

This situation is changing because dementia is rising up the research agenda in many countries, and funding streams are appearing not only for basic sciences research but also for social and organisational studies. In England we are seeing a particularly clear picture of how such a change in research priorities creates new opportunities and challenges for researchers. England has an increasingly integrated research and development process, with a dementia research agenda emerging from the National Institute of Health and Clinical Excellence (NICE), a government-funded UK wide research infrastructure developing for Dementias and Neurodegenerative Diseases (DeNDRoN) and substantial funding for programmes of dementia research being awarded by the National Institute of Health Research (NIHR).

This integrated approach is complemented by a new framework for allocating resources. The NIHR funds for dementia research are given to service provider organisations (the National Health Service) to manage, on the grounds that research needs to be embedded in practice rather than in Universities. Academics are drawn in as sub-contracted partners of the NHS. The multidisciplinary nature of dementia care is reflected in the requirement for programmes to include all appropriate disciplines, and the involvement of people with dementia and their carers/caregivers is similarly essential. In addition to the trials of drug treatments funded by industry and supported by DeNDRoN, the first wave of NIHR programmes had an explicit remit to improve services, and therefore favoured non-pharmacological therapies and studies that could demonstrate relevance for practice.

The ambitious, broad-ranging, five-year programmes funded by NIHR in the first round represent a welcome change in the approach of government to studies of dementia, but
they will pose interesting methodological challenges for health service researchers and their service provider partners. There are four particular difficulties arising from our programme that we present to this journal’s readership, both for information and to seek others’ experiences. They are the practicalities of assembling prospective cohorts, the strengths and limitations of routinely collected data compared with study-specific data, taking account of the Hawthorne effect of being involved in research, and possible reluctance to change within service providers.

The cohort. Creating a cohort of people with dementia and their carers/caregivers is necessary because researchers will need to show that their findings change both the ways in which services function and improve outcomes for people with dementia over time. Complex research programmes will contain different kinds of research projects, so enrolment of people with dementia and their carers may need to happen at least twice; once to agree to participate in research in principle, and again to take part in a particular project. The nature of dementia syndromes could make obtaining consent increasingly difficult as time passes, but the passage of time is essential to this type of research since it is the persistence of benefits from treatment or care that is so important.

The passage of time is a problem for funders who want to see relatively speedy returns from large-scale investments. Since the trajectory of dementia syndromes can last a decade or more, if we are to measure effects of service change on, say, end of life care, the cohort must enrol people with dementia at all stages of the disease process. Given the heterogeneity of older populations, the influence of prior experiences and personality on the expression of dementia syndromes and recent major changes in the economy and culture of later life, those people enrolled aged in their early seventies may be very different from those who are a decade or more older. Although the cohort will be neither an epidemiological one like that funded by the Medical Research Council (MRC)\textsuperscript{1} nor one that can necessarily map the ‘natural’ course of dementia syndromes, it will still yield important lessons for practice.
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If the tempo of research needs to be speedy, enrolling people with dementia will need to be done through the most productive channels. Logically, most people with dementia should be accessible through primary care, because their contact with specialist services (in the UK at least) may follow onset of symptoms by months or years and then be infrequent, if it occurs at all. In practice, projects recruiting through primary care find it difficult to reach their enrolment targets, for a variety of reasons, as two recent randomised controlled trials based in primary care have shown\(^2\) \(^3\). Enrolment through specialist services appears to be the quicker option, but runs the risk of excluding those not yet referred, some of whom may never encounter specialist services. Cohorts being assembled quickly will have to be recruited through both routes, acknowledging the weaknesses of each.

**Routine data or research data?** Everyone with dementia (in the UK) who has a diagnosis confirmed through specialist assessment will have information about their cognitive function and broader functional ability documented by services, but different instruments are used in different settings with a lack of standardisation. Documentation can be variable in quantity (especially for the views and experiences of people with dementia) and quality (especially in primary care). Many researchers are tempted to add more measurement tools to their studies, but this understandable desire creates two new problems for investigators. The first is that individual outcome measures in dementia are unsatisfactory, making use of a package necessary\(^4\). There is no easily standardised and relevant measure, equivalent to the HbA1c measure used for monitoring diabetes or the CD4 count used for HIV infection. The measures closest to being quasi-objective, the assorted cognitive function tests, may not be the most important in assessing the progress or impact of dementia or in measuring the effect of therapies or support.

The second problem is that the package of measures that might be preferred by investigators can be burdensome for people with dementia and their carers/caregivers, resulting in incomplete responses or withdrawal from the research. Missing data and attrition make interpretation of findings difficult. The need to reduce these risks might
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prompt further work on user-defined outcomes, which have long been overshadowed by validated measures with defined psychometric properties.

**Hawthorne effects.** Involvement in research is generally believed to improve outcomes, even if the person involved is in a trial arm which has no active treatment. This Hawthorne effect may not operate the same way in dementia studies as it does in, say, oncology. In cancer therapies there is hope of cure, or at least significant palliation, and so joining therapy trials makes sense to the person concerned. No such optimistic outcome is possible for the person with dementia, who has a progressive neurological disorder with an invariably fatal outcome. Being a research participant in such a context could be experienced positively or negatively, and research could for some be inadvertently disabling, highlighting their decline and so make the experience of the disease worse.

**Path dependency.** Services have a tendency to carry on functioning as they always have – so-called path dependency – and so might find translational research, with its explicit aim of changing services to improve the quality of care, threatening. Enquiry about service availability by people with dementia, or any aspect of their clinical care, may be experienced by professionals as a form of monitoring or audit. This might discourage practitioners from participating fully in research projects, especially if they feel overburdened with large caseloads or have to deal with negative Hawthorne effects arising from the research process.

These four challenges are not insurmountable but they will need to be addressed by open discussion and acknowledgment that there are no simple solutions. This can be done at several levels, notably in discussions between the research teams and the host NHS Trusts. Advisory groups could also provide opportunities to debate such issues with a group of stakeholders who will be alongside the research during its course. Documentation of how such changes unfold could be an important legacy for other studies, particularly if they are frank in reporting the debates and decision making. Withdrawal from any study will be important to monitor, to see if it is possible to unpick
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some of the reasons for any withdrawal, and this will apply as much to practitioners as to people with dementia and their carers/caregivers. A great deal is said about burdening study participants who are patients but little by comparison of the potential burdens on staff, who may be pulled in several directions by audit, research, quality assurance mechanisms and regulatory activity.

The development of this programme is ongoing and iterative. One of the other risks arising from the relatively richness of research opportunities is the temptation to think that little has taken place previously. We know that this is not the case but are aware that not all studies have been able to publish details of their processes, for example, because of shortages of resources or editorial bias. We welcome suggestions from others about how such problems have been addressed. The new research funding streams and structures in the UK create a unique opportunity to build up a research capacity that will hopefully make this more than a one-off event.

The EvIDem group (Evidence based Interventions in Dementia) has been awarded a National Institute of Health Research programme grant (RP-PG-0606-1005: Changing practice in dementia care in the community: developing and testing evidence-based interventions, from timely diagnosis to end of life). Other members include Jane Wilcock, Martin Knapp, Mark Griffin, Trish Labro, Clive Pilcher, Sara Whittaker & David Lowery.

REFERENCES

1 Basta NE, Matthews FE, Chatfield MD, Brayne C; MRC-CFAS. Community-level socio-economic status and cognitive and functional impairment in the older population Eur J Public Health. 2007 Jul 12; [Epub ahead of print]

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4 International Psychogeriatric Association Consensus conference: Defining and Measuring Treatment Benefits in Dementia, Canterbury 31st October -1st November 2006