NICE, devolution and drugs for dementia

There have been few more public and controversial chapters in the still relatively brief history of the National Institute for (Health and) Clinical Excellence (NICE) than in relation to recommendations concerning drugs for dementia. In 2001 an unusually prescriptive protocol (NICE, 2001) was drawn up limiting the initiation of acetylcholinesterase inhibitors for Alzheimer's disease to 'appropriate specialists', in practice old age psychiatrists and a few geriatricians. This advice was broadly accepted by the then newly established Health Technology Board for Scotland with a minimum of 'tartanisation' to protect the needs of more isolated and rural communities by defining a role for suitably interested and experienced GPs.

Current situation

One spin-off from treatment options was the emergence of memory clinics and other initiatives aimed at progressively earlier diagnosis. In some parts of the country these are already perceived as at risk and in terms of overall service delivery they are not without controversy (Pelosi et al, 2006). NICE's most recent recommendation (NICE, 2006) does slightly extend the duration of seemingly worthwhile treatment, in line with emergent clinical practice, but dramatically delays introduction of drug treatment until patients have reached a moderate stage of illness. NICE's level of reliance on the use of mini mental state examination (MMSE) scores for much more than they were ever intended (Folstein et al, 1975) also continues to cause concern and genuinely useful guidelines (Burns et al, 2006) on pharmacological management of dementia are at risk of being rendered largely irrelevant.

In the interim Health Technology Board for Scotland had been subsumed by NHS Quality Improvement Scotland and another body hosted by NHS Quality Improvement Scotland, the Scottish Intercollegiate Guidelines Network (SIGN), had issued clinical guidance strongly supportive of the use of anticholinesterases (SIGN, 2006). The Scottish Medicines Consortium had, however, anticipated both NICE and SIGN by ruling against the use of memantine in severe dementia despite a lack of alternatives or comparators. With Scotland's flagship policy on free personal care for older people a source of ongoing dispute between central and local government concerning levels of funding, and an increasing number of media reports raising concerns about the quality of UK long-term care, dementia has retained an unusually high profile of late.

Implications

Specific consideration will now need to be given to the support needs of patients and carers following diagnosis and while the 'necessary' level of deterioration in cognition is awaited. Hopefully the simultaneous release of NICE and Social Care Institute for Excellence (2006) clinical guidelines alongside the cost-effectiveness guidance will help focus attention and raise standards in this regard.

The superficially similar situation of deferring anti-Parkinsonian medication has a clinical rationale absent in Alzheimer's disease and hence even the high levels of depression associated with both patients and carers in Parkinson's disease may not be an accurate prediction of future trends in dementia. Anecdotally at least, MMSE practising was believed to have taken place previously in attempts to stay on medication and we may now see deliberately poor performances in bids to secure initiation. Thereafter any benefits of the medication will risk being exaggerated.

The extent of coordinated opposition to these measures has been the most broadly based in the mental health field since the alliance which formed in the face of the draft (English and Welsh) Mental Health Bill. There may even be legal uncertainty as to whether a cost effectiveness-based 'ban' conflicts with the maximization of capacity under the Adults with Incapacity (Scotland) Act 2000 or with the reciprocity principle of the Mental Health (Care & Treatment) (Scotland) Act 2003.

In very general terms it is hard to equate NICE's guidance with truly patient-centred care in dementia or with any concept of patient choice. Arguably the aspirations of values-based practice have more to offer a rounded and holistic health technology assessment than the more extreme stances to be seen within the doctrines of evidence-based practice. The precise legal and ethical meaning of 'This advice does not override the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer' (www.nhshealthquality.org) may ultimately need to be tested either in court or in front of the General Medical Council.

The future

With a unique process of consultation, adjustment to usual (NICE) procedure, re-consultation and appeal(s) now exhausted (give or take judicial review) it is necessary to consider whether those patients with more rapidly identified dementia are to be forced fully into the private sector. It would seem regrettable if older people who choose to use benefits intended for social or nursing care to instead secure a therapeutic trial of medication, or whose relatives offer to provide the funds, must also contend with pharmacy mark-ups and unnecessary duplication of medical assessment(s).

The legal (and perhaps political) ramifications of purchasing directly from the NHS, at cost, also require clarification. Media comparisons with other 'psychiatric' activity, such as methadone maintenance programmes, and with costly information technology adventures across the NHS in general are inevitable as are public worries over at least the perception of ageism.

Health economic methodology in dementia, particularly the role of the quality-adjusted life year (QALY), is still at a relatively early and rudimentary stage but it appears across the UK that the default position for patients and their carers is to be denied treatment while the theoretical arguments rage (Bosanquet, 2005). NICE and NHS Quality Improvement Scotland are belatedly beginning to grapple with the inherent problems of restricted focus on NHS costs but it will be a savage irony indeed if they are ultimately shown to have wasted public money in a condition whose total costs exceed those of heart disease, stroke and cancer combined.

Voters are likely to be unforgiving if dubious assumptions have simultaneously disenchanted professionals, distressed patients and demoralized the very carers upon whom so much depends. The commonly held view that things are somehow 'better' in Scotland is not justified in this instance and we can only wait to see whether the UK's international isolation on such a sensitive topic withstands ongoing scrutiny.

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KEY POINTS

- Both clinical guidelines and cost effectiveness guidance are now available in relation to dementia.
- A major new concept is that of deliberately waiting for patients with Alzheimer's disease to deteriorate to a predetermined level before treatment is recommended on health economic grounds.
- Important questions remain unanswered about doctors' ethical responsibilities and artificial obstacles to patients and carers simply paying (the NHS) for their drugs.
- The issues to be faced in Scotland are essentially the same as those in England and Wales.

COMMENTARIES

We must not forget the clinical issues

In his editorial Dr Findlay raises a number of important political issues. But just how important are the underlying clinical ones?

The first licensed dementia treatments have been generally disappointing. While we can all describe anecdotal reports of patients showing marked improvement, or delayed decline, we often fail to recognize the impact of non-drug interventions such being involved with our teams, and a different quality of support once the person is seen as ill, i.e. diagnosed as having a disease, rather than simply seen as 'going senile'.

This leads us to attribute most of any improvement to drug treatment. We then become aggrieved to an inappropriate degree when NICE recommends prescribing restrictions. The Alzheimer's Societies, our Royal Colleges and drug manufacturers put together appeals on our behalf, in the main along the lines of 'it just ain't fair'.

In this we do patients with Alzheimer's disease a great disservice. We are telling them that all we have to offer are drugs and by extension saying there is no point in attending us because our ability to prescribe them has been restricted.

The NICE guidelines are wrong. They are largely, as Dr Findlay points out, based on flawed economic arguments. Even the small improvements from drug treatment are worthwhile for some people. But we must also recognize the other benefits people with dementia get from seeing us, and must not allow this change to alter referrals to secondary care.

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Will Scotland pay the price for adopting the NICE appraisal?

Dr Findlay's comments are very wide ranging but correctly draw readers' attention to the implications of Technology Appraisal 111 (NICE, 2006). There is little doubt that old age psychiatry services throughout the country have over the past decade become increasingly skilled in the diagnosis and management of early dementia largely because the advent of effective treatment options. Many colleagues would suggest that crisis referrals have fallen as a consequence of service provision at earlier stages of dementia.

In Scotland there have been a number of keynote policies including free personal care and free nursing care. Concurrently, the number of the care home beds has stabilised (Scottish Executive, 2006a) and the number of NHS beds fallen consistently (Scottish Executive, 2006b). Although politicians may claim that free care has reversed the trend towards increasing institutional beds, the number of people receiving intensive home care (>10 hours per week) has shown only a small increase during the same period (Scottish Executive, 2006c). Given the fact that dementia is a major reason for admission to care homes, professionals involved in dementia care may be contributing substantially to the trends in care provision.

The question now is whether primary care will be sufficiently motivated to refer patients at an equally early stage. At present, none of the non-pharmacological treatments evaluated by SIGN 86 (SIGN, 2006) has a clear evidence base in mild dementia nor is the their cost effectiveness known. Consequently it will be extremely difficult for hard-pressed NHS trusts to justify spending money on these interventions.

Conversely, without the stimulus for early referral we may return to the bad old days of crisis intervention. Given the difference that free care makes to the funding of people in care homes by contrast to England, and the related potential difference in the cost-effectiveness of cholinesterase inhibitors, Scotland may yet pay dearly for the political imposition of therapeutic nihilism associated with the slavish adoption of NICE guidelines north of the border.

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Decisions are based on flawed models

There is an increasing pressure on budgets and correspondingly a greater emphasis on evaluating the cost-effectiveness of all therapies. While the greater drive for systematic meta-analysis of clinical trial data to inform evidence-based practice has many advantages, the greater complexity and competing goals of cost-effectiveness evaluations are more problematic.

This is particularly the case for the assessment of cost-effectiveness in the context of Alzheimer's disease and other dementias given the complexity of the illnesses, the impact on caregivers as well as the person with dementia, the variable and complex pattern of service use and the difficulty of conducting long term clinical trials. The symptomatic benefits of these treatments for people with Alzheimer's disease are evident from the results of more than 30 placebo controlled trials evaluated as part of the Cochrane reviews (Birks and Harvey, 2006; Birks et al, 2006; Loy and Schneider, 2006), with the mean level of cognitive performance remaining above baseline for 6–12 months in most studies and the perceived benefits to carers and people with Alzheimer's disease was further emphasized by 8000 responses of individual caregivers to NICE and in a survey of 4000 carers and people with dementia conducted by the Alzheimer's Society (2004). Restricting access to treatments that everyone agrees are clinically effective based on flawed and controversial models for quality-adjusted life years and inaccurate care costs seems inadvisable and is currently being legally challenged through the process of judicial review. As Dr Findlay highlights, it is difficult to see how this can be in the best interests of individual patients with Alzheimer's disease, and is likely to be challenged through the auspices of the General Medical Council. Alzheimer Scotland has consistently argued that there are significant additional issues in Scotland, and that NHS Quality Improvement Scotland should rework NICE's model to take into account contextual differences in Scotland, such as free personal care and the higher proportion of people with dementia in NHS continuing care.

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Perpetuating health inequalities: NICE guidelines are a blow to dementia care

NICE guidelines on the prescribing of cholinesterase inhibitors for the treatment of Alzheimer's disease threaten to widen the health inequalities and leave the UK further behind the rest of Europe in the diagnosis and treatment of dementia. Described by many as fundamentally flawed or unethical, the NICE guidelines have been particularly disappointing to the patients and carers of this cruel and devastating illness. The proportion of people with dementia rises to over 20% over the age of 80 years and the number of people suffering from dementia in the UK is expected to rise to over 870 000 by the year 2010 and 1.8 million by 2050. The UK ageing population and a relative decrease in the amount of family support and informal carers for people with dementia presents a massive challenge.

In terms of drug prescribing, NICE guidance recommends the use of three of the cholinesterase inhibitors in the treatment of people with moderate Alzheimer's disease but not in the early stages and the use of memantine as a part of clinical studies for people with moderately severe to severe Alzheimer's disease. NICE has based this decision on a wide range of data and evidence and concluded that these drugs do not make enough of a difference to recommend the use for treatment at all stages of Alzheimer's disease and also that these drugs have the potential to make a real difference only at the moderate stage of the illness.

It may be argued that the models used and the reliance and cost-effectiveness data may be unreasonable and not consistent with the overall impact on the care of Alzheimer's disease. The disease progression needs to be monitored not just on the basis of cognitive function models but should include wider issues as benefits to carers, carers' costs, improvements in behaviour symptoms, quality of life and the implications of long-term care. Withholding the prescribing of these drugs in mild to moderate stages, where patients and carers may value it most, may create ethical dilemmas for clinicians and their roles and responsibility in making the care of the patients their first concern. Unending appeals challenges and judicial reviews are not the way forward but training and education, understanding and raising awareness in improving attitudes may contribute towards meeting the challenges of long-term dementia care. We should not have to make a choice between drugs, support, care or quality of life. People with dementia have an equal citizenship right to all these.

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We must not give patients false hope

We note with interest the recent furore surrounding the new NICE guidance regarding drug treatment for Alzheimer's disease. On one side we have the pharmaceutical companies, the Alzheimer's Society, the British Geriatrics Society and the Royal College of Psychiatrists. On the other side we have NICE as the bad guy denying drugs to needy people.

While we will concede that there may be issues regarding the 3-year wait before reviewing the situation again, there is much to praise in the thoroughness of this document. We commend to the readers that, all that is needed to fully understand the judgement of NICE, is present there in the guidance.

The judgement has been criticized for using the MMSE (30 point scale) to decide and monitor treatment. The guidance does, however, recommend the use of other scales. The NICE provides extensive discussion of the various drug trials and in our opinion there is lack of robust evidence to support any claims.

There is no doubt that these drugs produce a definite and consistent effect, yet it is a very modest effect. Perhaps we are doing a disservice by siding with the drug companies on this issue. We cannot in good conscience provide our patients with false hope. These drugs will not stop the devastating nature of Alzheimer's disease, will not prolong life and the objective benefits may not even be sufficient to be noticed by carers.

Perhaps it is time for us to show some faith in the work done by NICE.

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Patients will suffer as a result of this decision

With the current NICE decision to restrict prescription of cholinesterase inhibitors to patients with moderate-moderately severe dementia, doctors are faced with a moral dilemma. What other terminal condition merits leaving the patient untreated until things get worse? In this instance clinical experience and user/carer reports have been undermined by a cost-effectiveness model that fails to recognize the true heterogeneity of the disease or its impact on others.

Dr Findlay clearly points out the dichotomy in which we in clinical practice now find ourselves. Best practice guidelines (SIGN, 2006) appear to carry little weight against the cost restrictions to be imposed as a result of the latest NICE guidelines. Professional autonomy is removed by technological appraisals that fly in the face of years of clinical expertise.

Supporting services and specialist clinics may all suffer the brunt of NICE's decision, with threats of funding being withdrawn from all but the most dependent. Clinicians have worked hard to ensure patients with dementia are identified early in the course of their disease and given the best possible chance of maintaining high levels of function for as long as possible. NICE appear to have ignored the 'human factor' as well as the 'professional voice'.

At the end of the day it is the very people the health service seeks to serve that suffer. We are increasingly bound by guidelines, protocols and cost savings. No longer can we say that we are doing the best for our patients.

We had the opportunity in Scotland to do something better for our patients, but NHS Quality Improvement Scotland insisted that health was a national, i.e. UK, issue. So much for independence. Our patients will suffer along with the rest of the UK.

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